**Interventional and Research Studies Serious Adverse Event Reporting Form**

(Barts Health NHS Trust/Queen Mary University of London

sponsored studies)

Please only send unexpected Serious Adverse Reactions to the JRMO

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| Report type: | | Initial □ Follow up □ | | | |
| **If the study is multi-site, the section below should be completed by the main site study coordinator prior to sending the template to the sites** | | | | | |
| Full title of the study: |  | | | | |
| Name of sponsor: | Barts Health □ Queen Mary □ | | | | |
| IRAS number: |  | | | | |
| Chief Investigator: | Name: Phone No:  Email address: | | | | |
| **This section should be completed by the SITE:** | | | | | |
| Principal Investigator: | Name:  Email address:  Phone No: | | | | |
| Site number: | Site name: | | | | |
| Date of site becoming aware of the event | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | | | |
| Patient ID: | Patient Age: | | Patient Gender: □ Male □ Female | | |
| Event Description (e.g. body site, symptoms) (\*please use separate form for each event) | Event\*: | | | | |
| Onset date of SAE: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | | Resolution date of SAE: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | |
| Severity: | Mild □ | | Moderate □ | | Severe □ |
| Type of SAE: | Results in death | | | | □ |
| Life threatening | | | | □ |
| Hospitalisation or prolongation of hospitalisation | | | | □ |
| Persistent or significant disability or incapacity | | | | □ |
| Congenital anomaly or birth defect | | | | □ |
| “Other” important medical event | | | | □ If “Other”, please describe: |
| Is the SAE likely to be a reaction to one of the IMPs in the trial? a | Procedure 1  (specify) | | | **□** Reasonably possible | **□** Not reasonably possible |
| Procedure 2  (specify) | | | Reasonably possible | **□** Not reasonably possible |
| Is the SAE expected? | Procedure 1  (specify) | | | **□ Expected** | **□ Unexpected** |
| Procedure 2  (specify) | | | **□ Expected** | **□ Unexpected** |
| Is the SAE due to the progression of an underlying illness? | Yes □ No □ | | | | |
| Action taken with study treatment and procedures: | Continued □ Reduced □ Increased □  Temporary stop □ Permanent stop □ | | | | |
| Did the PI withdraw the patient from the study? | Yes □ No □ | | | | |
| Outcome of SAE: | Resolved | | | □ | |
| Resolved with sequelae\* | | | □ | \*specify sequelae |
| Improved | | | □ | |
| Persisting | | | □ | |
| Worsened | | | □ | |
| Fatal | | | □ (Insert date of death \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | If fatal, copy of post-mortem available? Yes □ No □ |
| Unknown | | | □ | |
| Person completing the form if not the PI | Name:  Role:  Email address:  Signature: Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | | | |
| PI signature | Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | | | |

**For CI use only – unexpected serious adverse reactions**

|  |  |
| --- | --- |
| CI assessment: | Date reported to the REC:  \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) |